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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/284,935	Applicant(s) Takebe et al.
	Examiner Vera Afremova	Art Unit 1651
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>May 7, 2002</u></p> <p>2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>		
Disposition of Claims <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1, 2, 4, 5, 7, and 9-11</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>1, 2, 4, 5, 7, and 9-11</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>		
Application Papers <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
Priority under 35 U.S.C. §§ 119 and 120 <p>13) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a) <input checked="" type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input checked="" type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). <p>*See the attached detailed Office action for a list of the certified copies not received.</p>		
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p> <p>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
Attachment(s) <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____</p> <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p>		

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DETAILED ACTION

Claims 1, 2, 4, 5 and 7 as amended and new claims 9-11 (Paper No. 24 filed 5/07/2002) are pending and under examination.

Claims 3, 6 and 8 were canceled by applicants in the Paper No. 13 filed 4/17/2001.

Response to Arguments

Applicants' arguments filed 5/07/2002 have been fully considered but they are not persuasive for the reasons below.

Claim Rejections - 35 U.S.C. § 112

New matter

Claims 1, 2, 4, 5 and 7 as amended and new claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation such as “a substance that remains undigested up to the colon” in the claims 1, 2 and 5 has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of “a substance that remains undigested up to the colon”. There is a disclosure drawn to fermentation of cooked grains with koji molds for the purpose of producing material which promotes growth of beneficial microorganisms. However,

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the as-filed specification does not indicate what component is “a substance that remains undigested up to the colon” and when this ”substance” is made/obtained in the process of making the material. There is no support for the new genus such as “a substance that remains undigested up to the colon”. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of limitation such as “a substance that remains undigested up to the colon” in the claims 1 2 and 5 is considered to be the insertion of new matter for the above reasons.

Indefinite

Claims 1, 2, 4, 5 and 7 as amended and new claims 9-11 remain/are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as explained in the prior office action and for the reasons below.

Claims 1, 2 and 5 as amended are rendered indefinite by the phrase “a substance that remains undigested up to the colon” in the lack of definitions and proper disclosure in the as-filed specification. It is unclear as claimed and as disclosed what is this substance and when this substance is obtained/made in the process of preparing the claimed beneficial microorganism propagation-promoting material. The amended claims are indefinite and incomplete because the

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claimed product-obtained-by-method is intended to comprise “a substance that remains undigested up to the colon” but the method as claimed does not result in the production the intended substance.

All claims as amended remain indefinite for the reasons as explained in the prior office action with regard to the phrase “solid form grains” and with regard to the phrases “solid form” and “50% by weight of water”. Applicants appear to argue that the phrase “solid form” or solid form grains” means that the grains were not ground, pulverized or powdered. Yet, the claims are not so limited. Further, it is not particularly clear whether the use of either ground or not ground grains, for example, would makes a critical difference in the claimed method in order to obtain the intended material as it appears to be argued.

All claims as amended remain indefinite for the reasons as explained in the prior office action with regard to “beneficial microorganisms” and to removal/decomposing a “predetermined amount of phytic acid” and repeated herein.

Applicants’ arguments are based on the definitions in the as-filed specification. Yet, upon review of these definitions it is remains uncertain what is the source of beneficial microorganisms which are “contained in said resultant” and/or when they have been added. It is unclear what is encompassed by “removing/decomposing a predetermined amount of phytic acid”. Does it occur during fermentation/cultivation of koji molds without beneficial

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microorganisms or with beneficial microorganisms? What is intended by “predetermined amount of phytic acid”? When and how is it predetermined.

Claim 2 as amended remain indefinite with regard to “resistant” starch as explained in the prior office action. Applicants’ arguments are contradictory. Applicants appear to argue that the use of “resistant” starch is an essential element. But the applicants’ definitions for starch including resistant starch are the same as the generic definitions for starch in the Merck Index as argued. Thus, the differences and the criticality, if any, remain uncertain as claimed and argued.

With respect to the claims 4 and 7 Applicants argue that the term *Eumycetes* encompasses the use of yeast culture. However, although the claims are read in the light of specification, the specification is not read into the claims. The taxonomic group of *Eumycetes* comprise all fungi including yeast and koji mold or *Aspergillus* (see Ainsworth & Bibsy’s Dictionary of the Fungi at page 158) as explained in the prior art office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37CFR 3.73(b).

1. Claims 1, 2 and 4 as amended and new claims 9 and 10 remain/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,303,161 [D] as explained in the prior office action and repeated herein.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to a product or to a material with health-promoting effects obtained by hydrolysis/fermentation of grains or crops such as soybeans with koji molds in the presence of beneficial microorganisms including lactic bacteria. The limitations such as presence of at least some amounts of water during preparation of the claimed product/material and removal of phytic acid which are claimed in the instant application are inherently present in the claimed product of US 6,303,161 because US 6,303,161 clearly teaches that water was added during koji preparation and phytic acid was removed from the product of the invention of US ‘161 (for example: see at col.7, lines 44-55; col. 12, line 50-52; col.14, line 25). Further, the claimed product US’161 is required “to be formed so as to be absorbed by digestive tract” (see claim 9, for example) or it requires incorporation of therapeutically suitable absorbent such as, for example: starch which is required by the product of the instant claims. Accordingly, the claimed products are obvious variants. Thus, the inventions as claimed are co-extensive.

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Applicants' arguments are noted. However, since the patent US '161 and the present application are directed to substantially the same invention and have an inventor in common, the double patenting rejection is proper. Applicants have not provided a clear basis or justification for the allegation in the response that the double patenting rejection is improper. For example: applicants argue that none of claims 1-9 of US'161 discloses the decomposition of phytic acid (see response page 5, par. 4). This is not found convincing because the product-by-process of US'161 is drawn to a product obtained as the result of a "completion" of grain fermentation and hydrolysis in the presence of koji molds and beneficial lactic bacteria wherein the claimed "completion" of the process comprises decomposing/removing phytic acid in the same manner from the same material under the same treatment as in the instant application and claims particularly in the light of the as-filed specification definitions as disclosed and as argued. For example: see US'161 at col. 10, lines 1-4 or at col. 2, lines 48-52. Therefore, the claimed products are obvious variants and, thus, the inventions as claimed are co-extensive.

2. Claims 5 and 7 as amended and new claim 11 remain/is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-10 of copending Application No. 09/902,040 which is divisional of Application No. 09/194,657 now US 6,393,161 [D] as explained in the prior office action.

Applicants' arguments are noted. We apologize for any inconvenience related to the typing error in the numbers of the co-pending applications 09/902,040 and 09/284, 935.

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However, it should be understood by applicants that the instant application is not the divisional application of 09/194,657 now US 6,393,161 [D] but that the co-pending applicant 09/902,040 is the divisional of 09/194,657 now US 6,393,161 [D] since both applications have common inventor and both applications are directed to the substantially same invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 5 and 7 as amended and new claims 9 and 11 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,885,632 [B] as explained in the prior office action and for the reasons below.

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, inoculating grains with koji molds, adding water, cultivating the koji molds with beneficial microorganisms and decomposing phytic acid. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. The claimed material comprises “a substance that remains undigested up to the colon”. Some claims are further drawn to the use of beneficial

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microorganisms such as *Eumycetes*, lactic bacteria or bifidobacteria. Some claims are further drawn to the use of water content such as about 50%.

The cited patent is relied upon as explained in the prior office action and repeated herein.

5,885,632 [B] teaches a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating grains or crops such as soybeans with koji mold to create a koji preparation resultant, adding water to the resultant and removing phytic acid (fig. 1; col. 4, lines 35-45 or lines 52-57) wherein hydrolysis of the resultant is obtained by action of beneficial microorganisms contained in the resultant such as *Eumycetes* or fungal cultures or various koji molds (col. 6, lines 43-45). The effects of the US' 632 product are health-promoting effects related to propagation of beneficial microorganisms and/or other health-promoting effects such as carcinopreventive (see abstract). The amount of water which is added and/or present during hydrolysis is no more than 50 % or 40% (col. 6, line 25) as required by the presently claimed invention. Thus, the disclosure of US' 632 appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed.

With regard to the cited patent US 5,885,632 applicants argue that it does not teach the use of beneficial microorganisms such as *Eumycetes*, lactic bacteria and bifidobacteria (see response page 6, par. 2). However, the claimed invention (claims 4 and 7) requires the presence of at least one from the group of *Eumycetes*, lactic bacteria and bifidobacteria. The taxonomic group of *Eumycetes* comprise all fungi including yeast and koji mold or *Aspergillus* (see

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Ainsworth & Bibsy's Dictionary of the Fungi at page 158). Thus, the method of the cited patent US'632 utilizes the claimed representatives of *Eumycetes* whatever particular species might be intended. Applicants further argue that the phytic acid in the cited method is reduced by hydrolysis and not by cultivation. Yet, the claimed method encompasses both hydrolysis (claim 1, line 12) and cultivation (claim 1, line 16). Thus, it is not clear as argued what element or step leads to removing/decomposing of phytic acid in the claimed method. Moreover, the definitions related to "phytic acid" and/or to removal of phytic acid (page 12, lines 28-31) teach the removal or decomposing of phytic acid as liberating of phosphoric acid, for example. However, the disclosure of the cited US 5,885,632 provides that same interpretation of removing/decomposing phytic acid as liberating of phosphoric acid, for example: see US'632 at col. 9, lines 38-39. In addition, the cited method also encompasses steps of cultivation of microorganisms wherein the method results in the possession of a health-promoting product with reduced amount of phytic acid.

Finally, applicants argue that the cited US'632 does not teach "a substance that remains undigested up to the colon". However, the as-filed specification does not provide clear definitions of the intended substance. Therefore, the product and/or process of the cited patent which teaches that use of the same grains under the same treatment with the same koji microorganism and/or beneficial microorganism, is reasonably expected to comprise the same "substance" as the claimed and/or the intended "substance". For example: the starting grain material which is not ground, pulverized or powdered as presently argued is expected to

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comprise seed/grain covers which remain “undigested up to the colon” as presently claimed for unidentified “substance”.

Claims 1, 4, 5 and 7 as amended and new claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,308,284 [A] in the light of evidence provided by teaching of US 5,885,632 [B] or JP 7-23725 [N] for the reasons as explained in the prior office action and for the reasons below.

Claims as explained above.

The cited patent is relied upon as explained in the prior office action and repeated herein.

US 4,308,284 [A] clearly teaches a process and a product obtained by the process comprising steps of inoculating grains or crops (soybeans or rice or wheat) with koji mold belonging to *Aspergillus*, adding water and beneficial microorganisms such as lactic acid bacteria (abstract; col. 7, lines 5-30; col.3, lines 61-64; col.4, lines 44-46; col.5, line 21).

The step of removing phytic acid which is contained in the grains or hydrolyzed resultant is inherently present in the method/composition-obtained-by-method of the cited patent ‘284 in the light of evidence as taught by US 5,885,632 [B] or JP 7-23725 [N]. For example: the teaching of US 5,885,632 [B] demonstrates that koji molds have high phytase which are enzymes decomposing phytic acid and phytic acid is removed in the presence of added water during koji mold hydrolysis (see US’632 col. 9, lines 15 and col.8, lines 60-67). And the presently claimed method and composition-obtained-by-method are encompassing the use of identical koji molds,

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the use of identical grains/resultants and the use of additional water as it is taught by US 5,885,632. Therefore, the step of removing phytic acid appears to be inherently present in the method and composition-obtained-by-methods are directed to the use of identical koji molds and grains as claimed and as disclosed. The teaching of JP 7-23725 [N] is similar to US 5,885,632 [B] (see English abstract). Thus, the disclosure of US 4,308,284 appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed.

Applicants argument that the product-obtained-by-method of the cited patents US 4,308,284 [A] is a food preparation or soy sauce which is different from the presently claimed koji preparation is not convincing because it is unclear as claimed and as argued what makes that claimed product to be different from either final or intermediate soy product of the cited patent. Both the claimed and the cited products are obtained from the koji fermented grains or soybeans in the presence of beneficial lactic bacteria. Thus, they are reasonably expected to comprise “a substance that remains undigested up to the colon”, whatever differences might exist.

Claims 1, 4, 5 and 7 as amended and new claims 9 and 11 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,965,178 [E] in the light of evidence provided by US 5,885,632 [B] or JP 7-23725 [N] for the reasons as explained in the prior office action and for the reasons below.

Claims as explained above.

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US 5,965,178 [E] clearly teaches a process and a product obtained by the process comprising steps of inoculating grains or crops such as soybeans or rice or wheat (col. 2, line 57) with koji mold belonging to *Aspergillus*, adding water and beneficial microorganisms such as lactic acid bacteria (abstract; col. 4, example 1, line 31 and lines 47-51). The cited US '178 teaches the use of a large variety of beneficial microorganisms including lactic bacteria (col. 2, lines 40-50) and yeasts (col. 3, line 37) and it teaches the use of "solid" form or state for koji-fermented grain preparation (col. 2, line 63) as appears to be encompassed by the presently claimed invention. The step of removing phytic acid from the grains is inherently present in the method/composition-obtained-by-method of the cited patent '178 in the light of evidence as taught by US 5,885,632 [B] or JP 7-23725 [N] for the reasons as explained above. Thus, the disclosure of US' 178 [E] appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed.

Applicants argument that the product-obtained-by-method of the cited patent US 5,965,178 is a food preparation or a hydrolyzate seasoning which is different from the presently claimed koji preparation is not convincing because it is unclear as claimed and as argued what makes that claimed product to be different from either final or intermediate hydrolyzate seasoning product of the cited patent. Both the claimed and the cited products are obtained from the koji fermented grains in the presence of beneficial lactic bacteria. Thus, they are reasonably expected to comprise "a substance that remains undigested up to the colon", whatever differences might exist.

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Claims 1 and 5 as amended and new claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,329,370 [F] in the light of evidence provided by US 5,885,632 [B] or JP 7-23725 [N] for the reasons as explained in the prior office action and for the reasons below.

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, inoculating grains with koji molds, adding water, cultivating the koji molds with beneficial microorganisms and decomposing phytic acid. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. The claimed material comprises “a substance that remains undigested up to the colon”. Some claims are further drawn to the use of water content such as about 50%.

US 4,329,370 [F] teaches a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating solid form of grains with koji mold to create a koji preparation resultant, adding water or suspension with beneficial bacteria to the resultant (col. 8, lines 22-25). The step of removing phytic acid from the grains is inherently present in the method/composition-obtained-by-method of the cited patent ‘370 in the light of evidence provided by US 5,885,632 [B] or JP 7-23725 [N] for the reasons as explained above. The amount of water which is present during hydrolysis is no more than 50 % or 44.5% as required by the claimed invention and as disclosed by the cited patent (col. 8, line 18). The intended effects of the claimed product are health-promoting effects related to propagation of beneficial

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microorganisms. Thus, the disclosure of US' 370 appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed.

Applicants argue that the products-obtained-by-method of the cited patent US 4,329,370 are food preparations such as soy sauce, miso, etc. and, thus, they are different from the presently claimed koji preparation. However, it is unclear as claimed and as argued what makes that claimed product to be different from either final or intermediate koji preparations of the cited patent whether they are soy sauce and/or miso. Further, the clear definitions of "a substance that remains undigested up to the colon" are missing from the as-filed specification. Thus, the products of the cited patent which are obtained form the same starting materials as claimed invention by using the identical microorganisms including identical koji molds as in the claimed invention are expected to comprise the "substance" as intended for the claimed invention.

Applicants also argue that the cited patent '370 is silent with regard to phytic acid removal or decomposing. However, the cited method encompasses the use of the same starting material such as "solid form grains" as the claimed method according applicants' definitions as disclosed and as argued. The cited methods encompass the use of both hydrolysis and cultivation of the same microorganisms including koji molds. Thus, the cited method is reasonably expected to result in the removal/decomposing of phytic acid as intended for the presently claimed product/method in the light of the disclosure provided by US 5,885,632 [B] or JP 7-23725 [N]

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which teach that the phytic acid contained in the grains is removed or decomposed during cultivation of koji molds on the grains.

Applicants also argue (see response page 4) that the definitions related to “phytic acid” and/or to removal of phytic acid are disclosed in the instant specification on page 12, lines 28-31, wherein the removal or decomposing of phytic acid is interpreted as liberating of phosphoric acid under hydrolytic or enzymatic action of koji molds. The disclosure of the cited US 5,885,632, which are relied upon in the claim rejection, provides that same interpretation of removing/decomposing phytic acid as liberating of phosphoric acid, for example: see US'632 at col. 9, lines 38-39. Thus, whatever differences in the removal/decomposing of “predetermined” amounts of phytic acid or any amounts of phytic acid might exist, the same “removing/decomposing” of “a predetermined amount of phytic acid” during cultivation of koji molds is disclosed in the cited references.

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 5 and 7 as amended and new claims 9-11 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,885,632 [B] or US 4,308,284 [A] or US 5,965,178 [E] or US 4,329,370 [F] taken with JP 7-23725 [N], Remington [U], Merck [V], US

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5,118,626 [C] and JP 3-19686 [O] as explained in the prior office action and for the reasons below.

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, inoculating grains with koji molds, adding water, cultivating the koji molds with beneficial microorganisms and decomposing phytic acid. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. Some claims are further drawn to the use of beneficial microorganisms such as *Eumycetes*, lactic bacteria or bifidobacteria. Some claims are further drawn to the use of water content such as about 50%. Some claims are further drawn to incorporation of starch into the final product.

The cited references US 5,885, 632 [B], US 4,308,284 [A], US 5,965,178 [E] and US 4,329,370 [F] are relied upon for the disclosure of a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, inoculating grains with koji molds, adding water, cultivating the koji molds with other microorganisms and decomposing phytic acid. The cited references teach the use of koji molds and/or unidentified fungal cultures belonging to *Eumycetes* {US 5,885, 632 [B], US 4,329,370 [F]} or the use of koji molds, yeasts and lactic bacteria {US 4,308,284 [A], US 5,965,178 [E]} or the use of koji molds and unidentified beneficial bacteria {US 4,329,370 [F]} for fermentation of cooked grains and production of materials suitable for consumption and promoting health. The cited methods and products comprise the use of water content at amounts about 50 %. For example: see US

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4,329,370 at col.12, lines 16 or see US'632 at col. 6, line 25. Some of the cited references clearly teach step of removing/decomposing phytic acid during cultivation of koji molds {US 5,885, 632 [B]. Some of the cited references are considered to inherently include the step of decomposing/removing of phytic acid because they encompass the use of identical components which are treated in the manner identical to the method of US'632. In addition, the cited JP 7-23725 [N] is relied upon to demonstrate that the amounts of phytic acid are substantially reduced (removed or decomposed) during cultivation of koji molds on cooked grains (English abstract).

The cited references US 5,885, 632 [B], US 4,308,284 [A], US 5,965,178 [E] and/or US 4,329,370 [F] are lacking a particular disclosure related to incorporation of starch into a final fermentation product.

The reference by Remington [U] or Merck [V] teach starch or resistant starch as an absorbent suitable for any pharmaceutical preparations or food or edible product. US 5,118,626 [C] teaches that starch or resistant starch is progressively converted by microbial action of koji molds and lactic bacteria (col. 1, lines 18-21).

In addition, the patent JP- 3-19686 [O] is relied upon to demonstrate that a material obtained from grains fermented with koji molds is useful for promoting grow of beneficial lactic bacteria or bifidobacteria belonging to the genus of *Bifidobacterium*.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was to obtain the product as claimed with a reasonable expectation in success in promoting growth of beneficial microorganisms and/or sustaining health of living

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beings as intended by the claimed invention because the similar, if not identical, products and methods for making these products have been known and practiced in the prior art as demonstrated by the cited references {US 5,885, 632 [B], US 4,308,284 [A], US 5,965,178 [E] and US 4,329,370 [F]}. The products of the cited references which are obtained by grain fermentation with koji molds are disclosed as suitable for human and animal consumption. The cited products are taught as comprising the materials promoting growth of beneficial microorganisms {US 5,885, 632 [B], US 4,308,284 [A], US 5,965,178 [E], US 4,329,370 [F] and JP- 3-19686 [O]} . The cited products comprises components which sustain health of living beings by exhibiting carcinopreventive and osteoporosis preventing therapeutic effects {US 5,885, 632 [B]}. Further, one of skill in the art would have been motivated to add starch (or resistant starch) to the material, which is obtained by fermentation of grains with koji molds and other microorganisms, for the benefit of obtaining the pharmaceutical compositions since starch is a common component of various pharmaceutical compositions providing various health sustaining effects {Remington [U], Merck [V]} and it is also known as being digestible by beneficial microorganisms including koji molds and bacteria {US 5,118,626 [C]}. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

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With regard to the claim rejection under 35 U.S.C. § 103 applicants argue that the combination of the cited references is impossible to analyze and the hindsight is improper (see response page 9). However, the claimed invention is drawn to a fermentate of unknown constitution which is intended as a health-promoting/sustaining compositions which is neither limited to the presence of any particular ingredient derived from the grain fermented by microorganisms nor it is limited to the presence of living microorganisms in the final product. The components or “substances” of the claimed product are uncertain as claimed and they are unknown as disclosed.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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July 11, 2002.

Irene Ward
IRENE WARD
PRIMARY EXAMINER